AMENDMENT NO. 769

The PRESIDING OFFICER. Under the previous order, the Senate will now resume consideration of amendment No. 769 offered by the Senator from Arizona [Mr. KYL].

Mr. CHAFEE. Mr. President, I move to table the Kyl amendment and ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on agreeing to the motion to lay on the table amendment No. 769. The yeas and nays have been ordered. The clerk will call the roll.

The legislative clerk called the roll.

The result was announced—yeas 79, nays 21, as follows:

[Rollcall Vote No. 162 Leg.]

YEAS—79

Abraham	Frist	McConnell
Akaka	Glenn	Mikulski
Baucus	Gorton	Moseley-Braun
Bennett	Graham	Moynihan
Biden	Grams	Murray
Bingaman	Grassley	Nunn
Bond	Gregg	Packwood
Boxer	Harkin	Pell
Bradley	Hatch	Pressler
Breaux	Hatfield	Pryor
Bumpers	Heflin	Reid
Burns	Helms	Roth
Chafee	Hollings	Santorum
Coats	Hutchison	Sarbanes
Cohen	Inouye	Shelby
Conrad	Jeffords	Simon
Coverdell	Johnston	Simpson
D'Amato	Kassebaum	Smith
Daschle	Kennedy	Snowe
DeWine	Kerrey	Specter
Dodd	Kerry	Thomas
Dole	Lautenberg	Thompson
Dorgan	Leahy	Thurmond
Exon	Levin	Warner
Faircloth	Lieberman	Wellstone
Feinstein	Lugar	
Ford	Mack	

NAYS—21

Ashcroft	Domenici	Lott
Brown	Feingold	McCain
Bryan	Gramm	Murkowski
Byrd	Inhofe	Nickles
Campbell	Kempthorne	Robb
Cochran	Kohl	Rockefeller
Craig	Kyl	Stevens

So the motion to lay on the table the amendment (No. 769) was agreed to.

Mr. PRYOR. Mr. President, seeing no other Members of the Senate seeking recognition at this time, I would like to ask unanimous consent that I may be allowed to speak as in morning business, not to exceed 12 minutes.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMENDATION TO FORMER PRESIDENT BUSH

Mr. PRYOR. Mr. President, I thank the Chair for recognizing me and I thank the distinguished managers for allowing me to speak.

Mr. President, this morning's Washington Post and many television and radio news programs throughout America and perhaps the world, reported on what I would like to call a portrait in courage, and the person standing tall in that portrait was none other than former President George Bush.

Like many of my friends and family in Arkansas, former President Bush is a gun enthusiast. He is a long-time member of the National Rifle Association.

But like many other NRA members, President Bush was deeply offended by a recent NRA fundraising letter signed by Mr. Wayne LaPierre, the NRA's executive vice president. The LaPierre letter referred to several law enforcement officials: ''Jack-booted thugs who harass, intimidate, even murder law-abiding citizens.'' The NRA referred to Federal agents ''wearing Nazi bucket helmets and black storm trooper uniforms to attack law-abiding citizens.''

This irresponsible, inflammatory NRA fundraising letter incited the former President of the United States to the point that he wrote NRA President Thomas Washington to resign his NRA membership.

Former President Bush's letter reads as follows:

Your broadside against Federal agents deeply offends my own sense of decency and honor and it offends my concept of service to our country.

President Bush continues in his letter:

It indirectly slurs a wide array of government law enforcement officials who are out there day and night, laying their lives on the line for all of us.

Mr. President, I am asking unanimous consent that an excerpt from the story in the Washington Post about President Bush resigning his membership from the National Rifle Association be printed at this point in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

But his resignation letter was more personal than political.

''Al Whicher, who served on my [Secret Service] detail when I was vice president and president, was killed in Oklahoma City,'' Bush wrote. ''He was no Nazi. He was a kind man, a loving parent, a man dedicated to serving his country—and serve it well he did.

''In 1993, I attended the wake for ATF agent Steve Willis, another dedicated officer who did his duty. I can assure you that this honorable man, killed by weird cultists, was no Nazi.'' Willis was one of four federal agents killed in the initial February 1993 raid on the Branch Davidian compound near Waco, Tex.

''John Magaw, who used to head the [Secret Service] and now heads ATF, is one of the most principled, decent men I have ever know,'' Bush wrote. ''He would be the last to condone the kind of illegal behavior your ugly letter charges. The same is true for the FBI's able Director Louis Freeh. I appointed Mr. Freeh to the federal bench. His integrity and honor are beyond question.''

The letter concluded, ''You have not repudiated Mr. LaPierre's unwarranted attack. Therefore, I resign as a life member of NRA, said resignation to be effective upon your receipt of this letter. Please remove my name from your membership list. Sincerely, George Bush.''

GATT AND GENERIC DRUGS

Mr. PRYOR. Mr. President, when we in Congress voted on the GATT treaty recently, we all knew that we were breaking down trade barriers and leveling the playing field in international trade.

Make no mistake, I believe that Americans will benefit from this agreement when it is implemented in June. But never, Mr. President, in our wildest dreams or imagination, would we have ever thought we were voting to give special treatment and a $6 billion windfall to the prescription drug industry on one hand and higher drug prices to American consumers on the other. Yet that is exactly what is happening.

Mr. President, here is what has happened to bring us to this point today. Last year, the United States agreed under GATT to a new patent law, good for 20 years from filing. Our old patents were for 17 years, the effective date from their date of issue.

We also agreed under GATT to give existing patents the longer of the two patent terms. This extension applies to all industries.

At the same time, we knew that generic companies of all kinds all over America had already made significant investments based upon old patent expiration dates. These companies were prepared to introduce their competitively priced drug products just as the brand-name monopolies end.

We did not want to jeopardize the jobs and the factories which were at stake. So we decided under GATT to adopt a formula under which these generic companies could proceed with the introduction of their products if they paid the patent holders ''equitable remuneration'' for the period of time left on their patents.

Mr. President, here is where this story really begins. It just so happens that over 100 prescription drugs now protected by patents will be getting extra patent life under GATT.

For example, Glaxo's patent for the world's best selling drug, Zantac, would have run out December 5, 1995, but will now last until 1997. Generic drug companies have already spent millions of dollars to prepare to market lower cost, equivalent drugs on that date, giving consumers of America a tremendous price break.

But a small handful of brand-name pharmaceutical companies have objected. They are saying, ''Thank you for the extra patent life. We really appreciate that part of GATT. But you should know there is an obscure provision in U.S. drug law which we think protects us from the rest of the GATT treaty. We are sorry our generic competitors have invested heavily in their business, but they do not deserve the protections that are rightfully theirs under GATT. So we guess we will not have any competition for quite some time.''

This is what they have told the Food and Drug Administration. The pharmaceutical manufacturers have even threatened litigation against the Food and Drug Administration.

I am deeply concerned, Mr. President, because if they get their way at this time, they gain a multibillion dollar windfall—alone among the dozens of other industries and thousands of other companies complying rigidly with the GATT treaty.

Even worse, consumers now are going to have to pay double for these drugs. They will have to pay twice, Mr. President, as consumers and as taxpayers. The Federal Government and the State governments are going to pay an extra $1.25 billion for prescription drugs for older Americans under Medicare, veterans, low-income families and children, as well as the active duty military.

That will come out of our tax dollars. The American taxpayers will thus be paying more taxes so that a few brand-name drug companies can make more profits and block competition in the marketplace— forcing the American consumer to continue paying the highest drug prices in the world today.

Most important, I think, will be the effect on older Americans, Americans on fixed incomes, and Americans without adequate health insurance. They will feel the hurt of these soaring drug prices even more.

Mr. President, this chart is fascinating because it demonstrates very clearly that two of our best-selling drugs on the market are about to run out of patent protection, and should have generic competition by the end of this year.

Zantac, for example, is the leading drug for ulcers. It is manufactured by Glaxo. For a typical 2-month supply, the brand-name is $180. For a generic supply of 2 months, the cost is about $90. What we are going to see is, under GATT, an unintended consequence. Glaxo is going to receive a 19-month extension on their patent. This drug's price is not going to go down. There will be no generic competition with Zantac. We will see Zantac continue to soar in price. In fact, Glaxo is anticipating over a $1 billion windfall, because of this unintended consequence in GATT.

Do you think this brand-name drug, Zantac, is going to go down in price? Last year, Zantac's price grew 1½ times faster than inflation. The price for Zantac since 1989, only 6 short years ago, has increased 40 percent. What do you suppose is going to happen to that price if Zantac gains more than a year and a half of additional uncontested market exclusivity?

Mr. President, the intent of GATT, of course, was not to harm American consumers. The goal was to improve their standing in the world economy. The prescription drug marketplace today is one area where the American consumer has been particularly exploited as we have historically paid the highest price for drugs while subsidizing lower drug prices for consumers around the world.

This is why five of my colleagues and I have written to the Food and Drug Administration, asking the Food and Drug Administration to make the right decision—and that right decision is to allow generic drugs to come to the marketplace, offering competition to brand-named drugs which are about to receive an enormous unexpected and undeserved windfall.

This is a textbook case of a loophole resulting in an unwarranted windfall. No single industry deserves special treatment under GATT and today the pharmaceutical manufacturers of brand-name products are getting that special treatment at the expense of the American consumer. Should the Food and Drug Administration fail to provide the proper solution to this problem, I will immediately proceed with legislation to remedy this economic and this moral wrong. And I am hopeful my colleagues will join me.

Mr. President, I ask unanimous consent that an article appearing in Business Week magazine dated May 15, 1995, be printed in the RECORD, as well as letters to Dr. David Kessler, Commissioner of the Food and Drug Administration, from consumer, patient, health care, and trade groups supporting our concerns. These groups include the National Organization for Rare Disorders; Families USA and the Gray Panthers; AmeriNet, of St. Louis, MO, and Premier Health Alliance, of Westchester, IL; the National Association of Chain Drug Stores and the National Pharmaceutical Alliance.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[From Business Week, May 15, 1995]

A PATIENT MEDICINE CALLED GATT—FOR MAKERS OF BRANDED DRUGS, IT COULD PROVE A POWERFUL TONIC

(By John Carey)

It wouldn't be surprising if Robert J. Gunter took a dose of his own medicine. President of generic drugmaker Novopharm USA Inc., he has spent five years gearing up to produce a generic version of Glaxo Holdings PLC's blockbuster ulcer drug, Zantac. He even invested $40 million in a plant in Wilson, NC., built to pump out the low-cost version as soon as Glaxo's first patent expired in December.

Now, Gunter finds himself in the middle of stomach-churning patent battle. Glaxo and other brand name pharmaceutical giants are claiming that the General Agreement on Tariffs & Trade (GATT), signed by President Clinton in December, extends many of their patents, Zantac's among them. More important, they argue, the extended patent term gives them extra months—even years—of protection from competing generics.

While the case relies on complicated legal arguments, it boils down to whether provisions in GATT supersede a 1984 law that prevents the Food & Drug Administration from approving generics until the patent on a name brand expires. If the arguments prevail, more than 100 brand-name products will win an average of 12 months each of extra patent protection (table). A new study from the University of Minnesota estimates that the extra protection could give the drugmakers a windfall of $6 billion over the next 20 years. ''That's obscene,'' fumes Senator David H. Pryor (D-Ark.). ''American consumers are going to pay the bill.''

''EUREKA'' MOMENT

Pryor, a handful of other lawmakers, and the generics companies are fighting back. On Apr. 27, Pryor and five other senators asked the FDA to reject the brand-name companies' interpretation of GATT. Vows Novopharm's Gunter: ''If the pharmaceutical industry thinks generics will roll over and play dead on this, they have another think coming.'' The FDA's decision is expected within weeks, but the wrangling won't end then. FDA officials and executives on both sides predict that whatever the FDA decision, the loser will take the issue to court.

The high-stakes controversy wasn't anticipated when GATT was approved late last year. The agreement harmonized U.S. law with the rest of the world's by changing patent terms to 20 years from the initial filing instead of 17 years after being granted. Most companies thought the change applied only to new patents, but soon after passage, Glaxo's lawyers had a ''eureka'' moment. Poring over the legislation, ''we realized that for many of our existing products, patent life would be extended,'' says associate general counsel Marc Shapiro.

As a result, any patent that took under three years to win approval would have longer protection. Since the U.S. Patent Office took only 17 months to grant the first of two key patents on Zantac, the change would give the company an additional 19 months of protection for its top-selling drug.

But even as GATT changed patent terms, Congress tried to prevent harm to rivals that had been counting on the original expiration dates. Lawmakers inserted a clause permitting a company to introduce a competing product on the original patent expiration date if the company had made significant prior investments and if it paid the patent holder a royalty or some other form of ''equitable remuneration.'' While Jeremiah McIntyre, counsel for generic drugmaker Geneva Pharmaceuticals Inc., calls that ''a fair balance,'' on the theory that it's better to pay a royalty than not be allowed into the market at all, the provision would squeeze generic drugmakers' already thin profit margins.

OVERSIGHT?

Meanwhile, Glaxo, Bristol-Myers Squibb Co., and other brand-name companies are arguing that this escape clause shouldn't even apply to the drug industry. The reason, they say, is that it clashes with provisions in a 1984 U.S. generic-drug law that prevents the FDA from approving a generic drug until the brand-name patent expires. Unlike other instances where Congress amended existing laws to conform with GATT, it failed to resolve this conflict—implying an intent to keep existing law intact, says Glaxo's Shapiro. Pryor and others plead simple oversight. But the big drugmakers insist on claiming what they see as theirs.

In the coming fight, generic drugmakers face an uphill struggle. ''We have to be better organized, and spend more money to get our message across,'' says Bruce Downey, CEO of Barr Laboratories Inc., a generic drugmaker in Pomona, N.Y. As policymakers focus once again on rising health-care costs, the generic companies do have one potent message: If the brand-name companies win, Americans will pay billions more for drugs. Faced with the prospect of dramatically higher costs, ''I can't believe the [FDA] won't make the right choice,'' says Lewis A. Engman, president of the Generic Pharmaceutical Industry Assn. Robert Gunter can only hope he's right.

A WINDFALL IN THE MAKING

Pharmaceutical makers are seeking an average of 12 months' extra protection from generic competitors for more than 100 drugs.

[Dollars in millions]

Drug Company/Use	Months of added protection	Potential extra revenues because of lack of generic alternative
ZANTAC—Glaxo/ulcers	19	$1,000
MEVACOR—Merck/cholesterol-lowering	19	448
DIFLUCAN—Pfizer/antifungal agent	20	410
PRILOSEC—Merck/ulcers	17	586
CAPOTEN—Bristol-Myers Squibb/hypertension	6	101

Data: Prime Institute, University of Minnesota.

NATIONAL ORGANIZATION FOR RARE DISORDERS, INC.,
New Fairfield, CT, April 13, 1995.

Hon. DAVID KESSLER,
Commissioner, Food and Drug Administration, Rockville, MD.

DEAR DR. KESSLER: The National Organization for Rare Disorders, Inc. (NORD) is deeply concerned with the FDA's pending interpretation of the General Agreements on Tariffs and Trade (GATT) implementing legislation as it applies to pharmaceutical drug patents.

The branded pharmaceutical industry (represented by PhRMA) is seeking an extension of patents solely based on their desire to maximize profits. If these companies succeed in their attempt to limit consumer access to more affordable ''generic'' products, then millions of Americans will have no choice but to pay more for already over-priced drugs. NORD believes that Congress never intended to force American consumers to pay even higher prices for their prescription drugs.

While such patent extensions would significantly increase the cost of our Medicaid program, please consider the even greater burden this would place upon the millions of Americans who are refused health insurance—and in turn prescription drug coverage—because they are afflicted with a rare ''orphan'' disease.

GATT was intended to improve the welfare of American consumers through international trade—including the needs of patients who desperately rely on access to more affordable drugs. GATT was never intended to provide special treatment to any segment of the pharmaceutical industry.

Sincerely,

ABBEY S. MEYERS,
President.

FAMILIES USA FOUNDATION,
Washington, DC, April 10, 1995.

Dear Senator/Representative:

We understand that the FDA is currently reviewing its position on GATT language as it applies to the extension period on drug patents. If GATT rules are retrospectively applied to previously filed or issued patents, the average patent extension for currently marketed drugs would be more than 12 months. The FDA is considering regulations that would withhold approval of generic drugs covered by ''GATT-extended'' patents until the extension period has ended. This would force the American public to pay higher prescription drug prices.

Families USA recently studied price increases in the top-selling drugs used by Americans. In our report, *Worthless Promises: Drug Companies Keep Boosting Price*, we found that the prices consumers pay for the most commonly purchased drugs continue to increase faster than general inflation. Drug price increases are particularly harmful to senior citizens who have the greatest needs for drugs and are most likely to pay for them out of pocket.

Several of the brand-name drugs that could receive patent extensions are among the top-selling drugs used by Americans. Among the drugs whose patents would be extended are: Zantac, the top-selling drug used by Americans, which increased in price 38% from 1989 to 1994; Capoten, a blood pressure medicine which increased in price 65.3% from 1989 to 1994 and 4.9% last year; Pepcid, an ulcer medicine that increased in price 31.3% from 1989 to 1994; Mevacor, a cholesterol medicine which increased in price 27.8% from 1989 to 1994; and Prilosec, an ulcer medicine that increased in price 4.2% last year, and increased in price 7.5% (2.4 times as fast as inflation) in the year 1991 to 1992.

Generic drug products typically enter the market at prices 25% less than patented brand, and their prices are even less compared to the brand-name drug as generics further penetrate the market. Consumers desperately need relief from high drug prices.

A recent study by PRIME institute found that the extension would cost Medicaid about $1 billion. Federal and state governments will face more than $1.25 billion in added costs without generic drugs entering the marketplace.

We ask you to examine this issue and encourage the FDA to delay any ruling until the problem is fully investigated.

Sincerely,

JUDITH G. WAXMAN,
Director, Government Affairs.

GRAY PANTHERS PROJECT FUND,
Washington, DC, April 20, 1995.

Hon. DAVID KESSLER,
Commissioner, Food and Drug Administration, Rockville, MD.

DEAR DR. KESSLER: I am writing to you because we understand the FDA is reviewing its position on the language in GATT as it applied to extension periods on prescription drug patents. We understand that FDA is considering regulations that would prohibit the entry of generic drugs in the marketplace during this GATT extension period.

It is our position that this action would force the American public to pay higher prices for prescription drugs. It also seems to us, that the primary purpose of GATT is to create level playing fields and the best product at the lowest price to consumers. This action is contrary to that principle.

Many of the brand-name drugs that could receive extended patent protection are some of the most widely prescribed drugs used by Americans—especially the senior population. And these drugs continue to cost more and more each year. In a recent study by PRIME Institute of the University of Minnesota found that Medicare alone would incur about 1 billion added costs without the availability of generic drugs.

A generic prescription drug usually enters the marketplace at up to 25 percent less than the branded drug. To those individuals living on fixed incomes who already faced with rising health costs, the option to choose generic is very important.

Dr. Kessler, I trust that you will further investigate this issue and seriously consider the negative impact that prohibiting the availability of generic drugs on the American consumer.

Sincerely,

DIXIE HORNING,
Executive Director.

AMERIVET,
St. Louis, MO, April 25, 1995.

Hon. DAVID KESSLER,
Commissioner, Food and Drug Administration, Rockville, MD.

DEAR DR. KESSLER: The FDA is currently deliberating on an important issue that could force the American public to pay millions of dollars in higher prescription drug costs. The debate is over the interpretation of GATT legislation language as it pertains to patents on prescription drugs. This language extends the life of patents on a number of the country's most widely prescribed drugs, potentially generating a windfall to pharmaceutical companies at the expense of the American public.

As a group purchasing organization, the economic impact of the GATT patent extension and the projected cost to consumers is of great concern to us. We strongly urge you to do all you can to make available to consumers the generic drugs that may be delayed in reaching the market if the patents on brand-name drugs are extended.

As you realize, if a provider has a generic equivalent to substitute, the patient receives a cost savings over the brand-name drug. The cost to consumers for the currently marketed brand-name drugs is substantial, projected to be as high as $6,000,000, over potential generic equivalents. The cost will be incurred by the American public as well as Medicare, federal and state governments, employers, private insurers, and managed care firms.

We request that you seriously consider the enormous financial burden to the American public that would result from legislature preventing generic drugs from entering the marketplace during the GATT extension. We fully support your efforts in persuading the FDA to make lower-cost generic drugs available to consumers upon existing brand patent expiration.

Sincerely,

JOSEPH W. MULROY,
President.

PREMIER HEALTH ALLIANCE, INC.,
Westchester, IL, April 14, 1995.

Hon. DAVID KESSLER,
Commissioner, Food and Drug Administration, Rockville, MD.

Re GATT Extension Period and Drug Patents

DEAR HONORABLE KESSLER: It has been brought to my attention that certain language in the recently approved GATT legislation may have a negative impact on the price Americans will pay for prescription drugs in the near future. It is also my understanding that the branded pharmaceutical industry is currently pressuring FDA to make a ruling that would prevent generic drugs from entering the marketplace during this extension period—a decision that would place an enormous financial burden on the American health care system and public through higher priced drugs.

It is my firm belief that Congress did not intend for brand name pharmaceutical companies to be the recipient of a $6 billion financial windfall during this GATT extension period to be subsidized by health care providers and the American public.

This ''unintended consequence'' of the GATT language should not be passed on to hospitals and physicians that already are aggressively seeking ways to reduce healthcare costs, as well as private citizens.

I am personally asking you to seriously consider the negative implications that would result from legislation preventing generic drugs from entering the marketplace during the GATT extension. The access to generic drugs is vital to those Americans who need them the most and I trust you will

delay any ruling until further investigation into this matter has been made.

Yours truly,

BILL MAGRUDER,
Vice President, Pharmacy Program.

NATIONAL ASSOCIATION OF
CHAIN DRUG STORES,
Alexandria, VA, April 26, 1995.

Hon. DAVID KESSLER,
Commissioner, Food and Drug Administration, Rockville, MD.

DEAR DR. KESSLER: On behalf of the National Association of Chain Drug Stores (NACDS), I am writing to strongly urge that the Food and Drug Administration (FDA) recognize pre-GATT patent expiration dates for pharmaceuticals, and allow the approval of ANDAs for generic prescription pharmaceutical preparations where the sponsor of such application has made a ''substantial investment'' in the product prior to June 8, 1995, the date of implementation of the General Agreement on Tariffs and Trade (GATT). We understand that the FDA is currently considering whether GATT's implementing legislation provides such statutory authority. NACDS believes that it does.

NACDS represents America's chain drug store industry, and includes more than 160 chain companies in an industry that operates 30,000 retail community pharmacies. Chain pharmacy is the largest component of retail pharmacy practice, providing practice settings for more than 66,000 pharmacists. Our membership base fills over 60 percent of the more than two billion prescriptions dispensed annually in the United States.

We understand and support the importance of having generic prescription drugs available to consumers as soon as possible. Everyday, the availability of generic drugs enables the pharmacists who practice in our stores to help reduce overall prescription medication costs for populations that do not have prescription drug insurance. Among those who benefit from access to generic drugs are millions of older Americans and working poor, publicly-funded prescription drug programs such as Medicaid, and other third party prescription drug plans.

The impact that a misapplication of the GATT implementing legislation could have on the American public is significant. A recent study by the PRIME Institute at the University of Minnesota found that GATT provisions could result in an additional $6 billion in prescription drug expenditures in the United States because of the additional patent protections granted to brand name products, and the relative unavailability of lower-cost generic versions.

In summary, NACDS believes that the GATT agreement should not preclude the manufacturers of generic prescription drugs from bringing their products to market during the period of extended patent protection provided by GATT for brand name prescription drug products.

Sincerely,

RONALD L. ZIEGLER,
President and Chief Executive Officer.

NATIONAL PHARMACEUTICAL ALLIANCE,
Alexandria, VA, April 26, 1995.

Hon. DAVID PRYOR,
U.S. Senate, Washington, DC.

DEAR SENATOR PRYOR: The National Pharmaceutical Alliance (NPA) is an association of over 165 manufacturers and distributors of pharmaceutical preparations for human and veterinary use. Our members are dedicated to providing safe and affordable alternatives to the American public whenever health needs dictate the use of pharmaceutical products.

In December of last year, the congress ratified the Uruguay Round Agreements Act [P.L. 103–465] (URAA) of the General Agreement on Trade and Tariffs (GATT). This agreement created some fundamental changes to be made in U.S. patent law. The new law provides for patents to be in force 20 years from the date of application as opposed to the historical law of the United States which provided for patents to be in force for 17 years from date of approval. Congress, realizing that such a change would cause a financial hardship on companies that expected to enter the marketplace at the expiration of the old patent date, provided a remedy to allow competing products on the market.

Under H.R. 5110, the implementing language of GATT, companies that could show that a substantial investment had been made in a product could enter the marketplace at the pre-GATT expiry date. The respective companies then would work out an ''equitable remuneration'' during the life of the patent extension. This remedy will work for every industry except the generic pharmaceutical industry due to its regulation by the Food and Drug Administration. Since approvals for Abbreviated New Drug Applications (ANDAs) are governed by the Drug Price Competition and Patent Term Restoration Act of 1984, known as Hatch/Waxman, failure to change its provisions could prevent the FDA from granting approvals until after the patent extension has expired. We do not believe that Congress intended to treat the drug industry differently that other industries.

If the 109 generic pharmaceutical products inversely affected by GATT are kept off the market, the result could be an increased cost to the American consumer of over $6 billion and a cost of over $1.2 billion to Federal and State governments in higher Medicare and Medicaid costs. In 1995 alone, drugs such as alclometrasone dipr. (Alclovate), captopril (Capoten), and ranitidine HC1 (Zantac) could be unavailable to consumers in a generic version. Zantac alone could represent an additional cost to the consumers in excess of $1 billion during the time of the patent extension. At a time when both healthcare costs and government budgets are strained to the limit, it makes no sense for government to take any action that would fuel the growth in these expenditures.

In the ten years since its passage, the Hatch/Waxman legislation has done remarkably well at balancing the interests of proprietary drug companies and the generic drug industry. The public also has come to not only expect, but to rely upon, timely access to high quality, low cost alternatives to monopolistic priced name brand drugs.

NPA is pleased to see that members of Congress, such as yourself, are taking steps to correct this inequity in the law. Your actions are to be applauded and your decision to stand up for the American consumer is appreciated.

Sincerely,

CHRISTINE SIZEMORE,
Executive Director.

INTERSTATE TRANSPORTATION OF MUNICIPAL SOLID WASTE ACT

The Senate resumed consideration of the bill.

The PRESIDING OFFICER (Mr. THOMAS). The pending business is the Jeffords amendment No. 867.

The Senator from Michigan.

Mr. LEVIN. Mr. President, I ask unanimous consent I be allowed to proceed as in morning business for 3 minutes.

The PRESIDING OFFICER. Without objection, it is so ordered. The Senator may proceed.

THE NATIONAL RIFLE ASSOCIATION

Mr. LEVIN. Mr. President, our friend from Arkansas has brought to our attention the fact that former President Bush has decided to resign from the National Rifle Association because of its refusal to repudiate some statements which were made by a vice president of NRA in a fundraising letter. I join Senator PRYOR in commending former President Bush for his action. I am sure it is a difficult one for the President, as a decades-long member of the NRA and as someone who believes in so many of its programs and efforts to protect rights under the second amendment.

But what President Bush reacted to is what I think most Americans who have read this letter reacted to, which is a statement by Mr. LaPierre, among others, that the Clinton administration has authorized law enforcement personnel to murder law-abiding citizens.

Those are the words in the letter. It is an outrageous allegation about any American President or any American administration. I do not think 1 percent of the members of the NRA believe that the Clinton administration has authorized its agents, its Treasury agents, its FBI agents, its law enforcement agents, to murder law-abiding citizens. I wrote a letter to Tom Washington, whom I know. He is a resident of Michigan who was president of the National Rifle Association, urging him to retract that statement and some other allegations in that letter which are, I think, equally offensive, but at least that statement.

In his response to me, which I put in the RECORD yesterday or the day before yesterday, he really did not respond to the request. He simply acknowledged that sometimes fundraising letters have exaggerated rhetoric. But this is not a case of just exaggerated rhetoric. This is an allegation by one of the Nation's largest organizations that this administration has given the go-ahead to law enforcement personnel to murder—I am using the word murder because that is exactly the word that they used; indeed the letter underlines it, italicizes it, emphasizes it—to murder law-abiding citizens.

I do not think, again, anybody on this floor would think there is truth to that statement. I do not think 1 percent of the members, as I said, of the NRA believes there is truth to that statement. It is that kind of a statement, of a wild statement, of an irresponsible statement by a major organization, which is creating an unacceptable climate in this country, I believe. Is it the only statement? Of course not. Others have made outrageous statements, too. Do they have a right to make that statement under the first amendment? They do. I will defend it.